UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No. 10-4944 (PJS/LIB)

L.P.O.E., Inc., *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**DEFENDANTS' EXHIBIT A:**
	)	**RELEVANT PORTIONS OF**
The United States Drug Enforcement Administration, *et al.*,	)	**SENATE REPORT NO. 98-225**
	)	
	)	
Defendants.	)	

98TH CONGRESS
1st Session

SENATE

REPORT
No. 98-225

COMPREHENSIVE CRIME CONTROL ACT OF 1983

R E P O R T

OF THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ON

S. 1762

together with

ADDITIONAL AND MINORITY VIEWS

SEPTEMBER 14 (legislative day, SEPTEMBER 12), 1983.—Ordered to be printed

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manner consistent with section 502's amendments to 21 U.S.C. 841(b), discussed above. Each of the paragraphs of section 503 is discussed below.

Paragraph (1) redesignates current paragraphs (1) and (2) of 21 U.S.C. 960(b) as paragraphs (2) and (3) creates a new section 960(b)(1) which provides for heightened penalties for importation offenses involving large amounts of extremely dangerous drugs. This section is analogous to the new 21 U.S.C. 841(b)(1)(A) added by paragraph (1) of section 502 of the bill.

Paragraph (2) amends section 960(b)(2) (presently section 960(b)(1)), to consolidate the treatment of offenses involving all Schedules I and II substances except lesser amounts of marihuana and hashish, as was done with respect to section 841(b)(1) in section 502 of the bill. The current 15-year level of imprisonment is retained, but the fine is elevated from $25,000 to $125,000, as was done in section 502 of the bill with respect to the analogous offenses punishable under 21 U.S.C. 841(b)(1).

Paragraph (3) amends current 21 U.S.C. 960(b)(2) (redesignated as section 960(b)(3) in this section), which now governs offenses involving all controlled substances other than Schedule I and II narcotic drugs. As amended, this section would continue to govern violations involving lesser amounts of marihuana and hashish, and all Schedule III, IV, and V substances, would retain the current five-year maximum term of imprisonment, but would raise the current fine of $15,000 to $50,000. Unlike 21 U.S.C. 841(b), 21 U.S.C. 960 does not provide separate penalties for offenses involving Schedule IV and V substances.

SECTION 504

Section 504 amends 21 U.S.C. 962 to permit prior State and foreign, as well as Federal, felony drug convictions to be considered for the purpose of this section's enhanced sentencing for repeat drug offenders. As noted above, various provisions of 21 U.S.C. 841(b) were amended in a similar manner.

PART B—DIVERSION CONTROL AMENDMENTS

1. In general and present Fedeal law

Part B of Title V (Sections 505–526) is designed to strengthen the government's authority to regulate controlled substances. In particular, the amendments set out in Part B are intended to address the severe problem of diversion of drugs of legitimate origin into the illicit market.

Diversion of legally produced drugs into illicit channels is a major part of the drug abuse problem in the United States. It is estimated that between 60 and 70 percent of all drug-related deaths and injuries involve drugs that were originally part of the legitimate drug production and distribution chain.[17] Also, diversion of legally produced drugs often evidences the same sort of large-scale trafficking more commonly associated with the trade in wholly illicit drugs. For example, the Justice Department informed the

[17] Crime Control Act Hearings (statement of the Department of Justice, p. 77).

Committee that 21 practitioners registered to dispense controlled substances convicted as the result of an investigation named "Operation Script" were responsible for the diversion of approximately 21.6 million dosage units of controlled substances.[18]

Illicit diversion of drugs of legal origin is not a new phenomenon. Indeed, the passage by the Congress in 1970 of the Controlled Substances Act (CSA)[19] was very much a response to a diversion problem that had grown so severe at that time that nearly half of all legitimately produced amphetamines and barbiturates were being diverted to illicit channels.[20] In order to address this problem of drug diversion, the CSA provided for a "closed" system of drug distribution for legitimate handlers of controlled drugs.

Under the Controlled Substances Act, drugs are controlled through the exercise of the Attorney General's rulemaking authority. Based on the severity of the abuse potential of a particular drug, the extent to which it leads to physical or psychological dependence, and has an accepted medical use, a drug is placed on one of five schedules.[21] For example, a Schedule I substance is one that has a high potential for abuse and no accepted medical use, while a Schedule V substance is one with a relatively low potential for abuse and dependence and an accepted medical use for treatment.[22]

Those who are to manufacture, distribute, import, export, dispense and administer controlled substances legally must obtain a registration from the Attorney General. Those registered must adhere to certain recordkeeping and reporting requirements that permit monitoring the flow of controlled substances within the "closed" system. In keeping with the nature of the drug diversion problem at the time of its enactment, the CSA's regulatory scheme focuses most sharply on the activities of manufacturers and distributors of controlled substances, with lesser controls applicable to practitioners, that is, those who dispense, prescribe, or administer controlled substances to ultimate users.

In many respects, the current provisions of the Controlled Substances Act have been quite effective in meeting the diversion problem at the manufacturer and distributor levels.[23] For the most part, current law generally provides strong authority to regulate these levels of the "closed" distribution chain. Registration to manufacture or distribute controlled substances is issued only when clearly consistent with the public interest. Administrative, civil, and criminal enforcement tools generally operate effectively at this level and mechanisms to control diversion by manufacturers and distributors have largely proven adequate.

Unfortunately, experience under the Controlled Substances Act over the past decade has demonstrated that the same strong regulatory authority to maintain a "closed" distribution chain does not exist at the practitioner level. Yet, it is estimated that 80 to 90 per-

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[18] *Ibid.*
[19] 21 U.S.C. 801 et seq.
[20] H.R. Rept. No. 91-1444, 91st Cong., 2d Sess., reprinted in 1970 U.S. Code Cong. & Ad. News, 4566, 4572.
[21] 21 U.S.C. 811 and 812.
[22] 21 U.S.C. 812(b) (1) and (4).
[23] Crime Control Act Hearings (statement of the Department of Justice, p. 79).

cent of all current diversion occurs at this level.[24] Under current law, the grounds for denial or revocation of the registration of a practitioner are very limited. Indeed, the Attorney General must presently grant a practitioner's registration application unless his State license has been revoked or he has been convicted of a felony drug offense,[25] even though such action may clearly be contrary to the public interest.

Thus, one weakness of current law is that it has not been adequate to address the shift in the source of diversion from the manufacturer and distributor levels to the practitioner level. Over the past decade other weaknesses of the Controlled Substances Act have also surfaced as ambiguities and loopholes in the law have come into focus. For example, the procedural requirements for controlling a drug under 21 U.S.C. 811 have proven sufficiently time consuming that they preclude a swift response when an as yet uncontrolled drug rapidly enters the illicit market and creates a significant health problem. Absence of adequate recordkeeping requirements has inhibited efforts to control the diversion of highly abused nonnarcotic drugs. Insufficient authority exists to safeguard dangerous drugs held by persons whose registration has expired or who have gone out of business. Authority to control the import and export of controlled substances has proven too limited in certain respects.

At the same time, certain regulatory requirements of current law have proven overly stringent. Annual registration requirements for practitioners, who comprise the overwhelming majority of all controlled substances registrants and who are generally law-abiding, has become an excessive regulatory burden for both practitioners and the government. Insufficient authority to exempt from controls substances that have no or low abuse potential or that are needed for scientific and research purposes has resulted in unnecessary regulation.

The diversion control amendments of Part B of Title V of the bill are designed to address this variety of problems that have arisen in the more than a decade of experience under the Controlled Substances Act. In addition to addressing the more recent problem of maintaining the intended "closed" system at the practitioner level, they strengthen other aspects of current regulatory authority where necessary and at the same time give additional regulatory flexibility where current law has proven too rigid. Also included is a grant-in-aid program through which financial assistance could be given to States and localities in order to increase their capacities to respond to the drug diversion problem.

2. Provisions of the bill, as reported

SECTION 505

Section 505 amends 21 U.S.C. 802, which sets forth the definitions of terms used in the Controlled Substances Act,[26] first, by

[24] *Ibid.*
[25] See 21 U.S.C. 823(f) and 824(a).
[26] 21 U.S.C. 801 et seq.

adding a definition of the term "isomer," and second, by providing an expanded and more detailed definition of the term "narcotic drug."

An isomer of a drug is a different compound, but one which has the same number and kind of atoms. Thus, although an isomer is not strictly identical to the drug, it is so similar that it has many of the same chemical and physical properties of the drug. Isomers include optical, positional, and geometric isomers. In many instances, substances listed in Schedules I and II (see 21 U.S.C. 812(c)) include drugs and their isomers. Moreover, international treaty obligations of the United States, such as the 1961 Single Convention on Narcotic Drugs and the 1971 Convention of Psychotropic Substances, require control of certain isomers of dangerous drugs.

Because of the absence of a clear definition of what is meant by the term "isomer," clandestine manufacturers have attempted to circumvent the law by manufacturing positional and geometric isomers of hallucinogens in Schedule I and optical and geometric isomers of cocaine. Indeed, this practice with respect to cocaine has given rise to frequent assertion of what is termed the "isomer defense." [27] Isomers of dangerous drugs often elicit similar harmful pharmacological effects, and have no legitimate commercial use. The definition of the term "isomer" set out in section 505's amendment of 21 U.S.C. 802 will assure that those isomers requiring control under the Controlled Substances Act are clearly covered by the statute.

Section 505 amends the definition of "narcotic drug" currently appearing in 21 U.S.C. 802(16) [28] in the following ways. First, the definition of opium and opiates is unified in a more concise paragraph (A). Second, poppy straw and its concentrate (not used commercially in the United States at the time of enactment of the Controlled Substances Act) is added to the definition. Third, coca leaves are more clearly described. Fourth, cocaine and ecogine [29] are given a detailed specific listing within the definition of "narcotic drug." (This also assures consistency with the Single Convention on Narcotic Drugs.)

The definitional amendments in section 505 are designed largely to clarify the scope of current law and cure any potential loopholes or ambiguities. There are no significant changes in the scope of substances subject to control.

SECTION 506

Section 506 amends 21 U.S.C. 811 by adding a new subsection (h) that would permit the temporary emergency scheduling of a substance which presents an immediate danger to public safety. Under current 21 U.S.C. 811, before a substance may be designated for control under the Controlled Substances Act by the Attorney General, the Secretary of Health and Human Services (HHS) must first submit a scientific and medical evaluation of the substance,[30] and

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[27] The "isomer defense" was soundly rejected in *United States* v. *Fince*, 670 F.2d 1356 (4th Cir. 1982).

[28] Because of the addition of the definition of "isomer," the definition of "narcotic drug" is redesignated in section 505 of the bill as 21 U.S.C. 802(17).

[29] Ecogine is another compound found in coca leaves.

[30] 21 U.S.C. 811(b).

the prior notice and hearing requirements of the Administrative Procedure Act (5 U.S.C. 500 *et seq.*) must be met as provided in 21 U.S.C. 811(a). Historically, even when given a high priority, such as in the case of the rescheduling of PCP and the scheduling of its analogs, a scheduling action under current law takes at least six months, and often as long as a year. During the interim between identification of a drug that presents a major abuse problem and the eventual scheduling of the substance, enforcement actions against traffickers are severely limited and a serious health problem may arise.

Under new subsection (h), the Attorney General would be permitted to control a substance on a temporary basis without meeting the prior notice and hearing requirements of 21 U.S.C. 811(a) or the Department of Health and Human Services evaluation requirement of 21 U.S.C. 881(b), if such action was "necessary to avoid an imminent hazard to the public safety." In issuing a temporary ruling under this new provision, the Attorney General would be required to consider only those factors set out in 21 U.S.C. 811(c) (4), (5), and (6) which relate to the history, current pattern, scope, duration and significance of abuse of the substance, and the risk it poses to the public health. New subsection (h)(1) specifically focuses attention on actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or marketing.

The Attorney General is to notify the Secretary of Health and Human Services of the proposed temporary scheduling of any drug or substance under new subsection (h). The Secretary may object to the temporary scheduling of the substance within thirty days. However, unless the Secretary has currently available evidence relating to the lack of abuse potential of the substance, his considerations are confined to the same factors which are to have been assessed by the Attorney General in his determination. Should the Secretary object to the temporary scheduling his decision is binding on the Attorney General.[31] Temporary scheduling under new subsecton (h) is to expire after one year, but the Attorney General may extend the temporary scheduling for an additional period of six months during the pendency of routine control proceedings under section 811(a).

If a substance is subject to the temporary control provided in new subsection (h) of 21 U.S.C. 811, the penalty for its illegal manufacture, distribution, dispensing, or possession with intent to engage in such conduct, is to be the same as that provided in 21 U.S.C. 841(b)(1)(C) for Schedule III substances. Of the regulatory requirements of title II, Part C of the Controlled Substances Act, only the registration and reporting and recordkeeping requirements of 21 U.S.C. 822 and 827 are to apply to temporarily scheduled substances.

The new emergency control authority provided in section 506 of the bill is designed to allow the Attorney General to respond quickly to protect the public from drugs of abuse that appear in the illicit traffic too rapidly to be effectively handled under the lengthy

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[31] The decision of the Secretary of Health and Human Services is binding only with respect to the temporary scheduling of the substance, and not with respect to any subsequent control proceedings under 21 U.S.C. 811(a).

routine control procedures. In such situations, law enforcement considerations and the need to protect the public may require action that cannot await the exhaustive medical and scientific determinations ordinarily required when a drug is being considered for control. The emergency control amendment of section 506 permits such action on a temporary basis until the more extensive scheduling procedures required under current law can be met.

SECTION 507

Under current 21 U.S.C. 811(g)(1), the Attorney General may exempt from a schedule of control certain compounds, mixtures, or preparations containing stimulant or depressant substances. Section 507 of the bill amends this provision of current law to clarify and expand the exemption authority of the Attorney General. The compounds, mixtures, and preparations which may be excluded are those that do not present any significant potential for abuse because of the nature of their preparation. As amended, 21 U.S.C. 811(g)(1) would specify three categories of compounds which may be exempted from the controls of the Controlled Substances Act. These are "exempt over the counter preparations," "exempt prescription preparations," and "exempt chemical preparations."

As defined in paragraphs (A), (B), and (C) of section 811(g)(1), as amended, "exempt over the counter preparations" are those containing a nonnarcotic controlled substance which may be lawfully sold over-the-counter under the Federal Food, Drug and Cosmetic Act; [32] "exempt prescription preparations" are those containing a nonnarcotic controlled substance which is combined with one or more noncontrolled active ingredients so that the potential for abuse is vitiated; and "exempted chemical preparations" are compounds, mixtures, or preparations which are not for administration to humans or animals and do not present any significant abuse potential. Section 507's expansion of the authority to exempt substances from control which do not pose a significant threat to public health and safety allows a reduction in unnecessary regulatory burdens. Because the concept of "exempt prescription preparations" added to the exemption authority under 21 U.S.C. 811(g) is analogous to the basis for exemption set out in current 21 U.S.C. 812(d), the separate exemption authority under section 812(d) is deleted.

SECTION 508

Section 508 amends 21 U.S.C. 822(a) by authorizing the Attorney General to establish a registration period for practitioners that may be up to three years in duration, but not less than one year. Currently, practitioners dispensing controlled substances, as well as manufacturers and distributors of controlled substances, must register annually. The annual registration requirement for manufacturers and distributors is retained.

Practitioners, those who dispense controlled substances to ultimate users, now comprise almost 98 percent of all registrants.[33]

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[32] 21 U.S.C. 301 et seq.

[33] Crime Control Act Hearings (statement of the Department of Justice, p. 83).

Thus, this amendment will allow substantial cost and time savings to both practitioner registrants and the government by alleviating the burden of annual registration.

SECTION 509

Improper diversion of controlled substances by practitioners is one of the most serious aspects of the drug abuse problem. However, effective Federal action against practitioners has been severely inhibited by the limited authority in current law to deny or revoke practitioner registrations. Under current 21 U.S.C. 823(f), the Attorney General must register a physician, pharmacy, or other practitioner as long as the practitioner is authorized to dispense controlled substances in the State in which he practices. The authority to deny or revoke a practitioner's registration under current 21 U.S.C. 824(a) is limited to instances in which the registrant has (1) materially falsified an application, (2) been convicted of a State or Federal felony relating to controlled substances, or (3) had his State registration or license suspended, revoked or denied.

The current limited grounds for revoking or denying a practitioner's registration have been cited as contributing to the problem of diversion of dangerous drugs.[34] In addition, because of a variety of legal, organizational, and resource problems, many States are unable to take effective or prompt action against violating registrants.[35] Since State revocation of a practitioner's license or registration is a primary basis on which Federal registration may be revoked or denied, problems at the State regulatory level have had a severe adverse impact on Federal anti-diversion efforts. The criteria of prior felony drug conviction for denial or revocation of registration has proven too limited in certain cases as well, for many violations involving controlled substances which are prescription drugs are not punishable as felonies under State law. Moreover, delays in obtaining conviction allow practitioners to continue to dispense drugs with a high abuse potential even where there is strong evidence that they have significantly abused their authority to dispense controlled substances.

Clearly, the overly limited bases in current law for denial or revocation of a practitioner's registration do not operate in the public interest. Section 509 of the bill would amend 21 U.S.C. 824(f) to expand the authority of the Attorney General to deny a practitioner's registration application. Under 21 U.S.C. 824(f), as amended by section 509 of the bill, the Attorney General would be required to register a practitioner authorized under State law to dispense or conduct research with controlled substances unless he made a specific find that registration would be "inconsistent with the public interest." Whether registration is in the public interest is to be based on consideration of the following factors: (1) the recommendation of the appropriate State licensing board or professional disciplinary authority; [36] (2) the applicant's past experience in dis-

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[34] General Accounting Office, *Retail Diversion of Legal Drugs—A Major Problem With No Easy Solution* (Washington, D.C. 1978).

[35] Drug Enforcement Administration, *Comprehensive Final Report on State Regulatory Agencies and Professional Associations* (Washington, D.C. 1977).

[36] Thus, it would no longer be necessary that the State authority have in fact revoked the practitioner's license or registration before Federal registration could be denied.

pensing or conducting research with respect to controlled substances; (3) the applicant's prior conviction record concerning controlled substances offenses; [37] (4) compliance with applicable State, Federal, or local controlled substances laws; and (5) other factors that are relevant to and consistent with the public health and safety.[38]

The amendment set forth in section 509 will continue to allow the Attorney General to routinely register most practitioner applicants. However, in those cases in which registration is clearly contrary to the public interest, the amendment would allow a swift and sure response to the danger posed to the public health and safety by the registration of the practitioner in question. The broader considerations for registration of practitioners set out in section 509 of the bill are similar to those applicable under current law to registration applications on the part of the manufacturers and distributors of controlled substances.[39] However, the amendment would continue to give deference to the opinions of State licensing authorities, since their recommendations are the first of the factors to be considered with respect to practitioner applications.[40]

SECTION 510

Section 510 amends 21 U.S.C. 824(a) to add to the current bases for denial, revocation, or suspension of registration a finding that registration would be inconsistent with the public interest on the grounds specified in 21 U.S.C. 823, which will include consideration of the new factors added by section 509, as discussed *supra*.

SECTION 511

Section 511 amends 21 U.S.C. 824(f) by adding a new provision that would authorize the Attorney General to place under seal any controlled substances owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business. The controlled substances are to be held for the benefit of the registrant or his successor in interest for 90 days. At the end of this 90-day period, the Attorney General may dispose of the controlled substances in accordance with 21 U.S.C. 881(e), which governs the disposal of controlled substances forfeited to the United States.

The amendment set forth in section 511 is designed to give the Attorney General necessary authority to safeguard quantities of controlled substances which pose a risk of theft or hazard to the public health and safety because they are in the possession of those no longer registered or who have gone out of business. This authority is in addition to the existing authority under current 21 U.S.C.

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[37] The criteria of prior conviction for a drug offense would thus no longer be limited to felony convictions.

[38] By virtue of the amendment to 21 U.S.C. 824(a) in section 510 of the bill, these factors could also serve as the basis for revocation or suspension of registration.

[39] See 21 U.S.C. 823 (a), (b), (d), and (e).

[40] Registration of a physician under the Controlled Substances Act is a matter entirely separate from a physician's State license to practice medicine. Therefore, revocation or registration only precludes a physician from dispensing substances controlled under the Controlled Substances Act and does not preclude his dispensing other prescription drugs or his continued practice of medicine.

824(f) to forfeit controlled substances held by those whose registration has been revoked or suspended.[41]

SECTIONS 512 AND 513

Sections 512 and 513 amend 21 U.S.C. 827(c)(1) which sets forth exemptions from the general recordkeeping requirements imposed on practitioners with respect to their prescribing, dispensing, or administering controlled substances. These amendments eliminate the current artificial distinction for purposes of recordkeeping between narcotic and nonnarcotic controlled substances. Section 512 amends 21 U.S.C. 827(c)(1)(A) so that it applies to the prescribing of all controlled substances by practitioners. As amended, this provision would exempt from practitioners recordkeeping requirements only the prescribing of controlled substances "in the lawful course of their professional practice." As amended by section 513, 21 U.S.C. 827(c)(1)(B) would further exempt practitioners from the requirement of keeping records concerning the administering of controlled substances, unless the practitioner "regularly engages in the dispensing or administering of controlled substances and charges his patients * * * for substances so administered." This same formulation applies under current 21 U.S.C. 827(c)(1)(B) to a practitioner's dispensing of nonnarcotic controlled substances.

The additional recordkeeping burden on practitioners resulting from the amendments set out in sections 512 and 513 will be minimal, but the increase in accountability will be a major law enforcement improvement. The present lack of recordkeeping with respect to the dispensing of nonnarcotic drugs is a serious problem in detecting illicit sale and diversion by practitioners. These amendments eliminate this loophole while still preserving a recordkeeping exemption for prescriptions and limited administration of controlled substances within the practitioner's office.

SECTION 514

Section 514 amends 21 U.S.C. 827 by adding a new subsection that would require registrants to report a change of professional or business address. This will facilitate the transmittal and prompt response to applications for registration renewal. Also, in light of the amendment in section 508 of the bill allowing the registration of practitioners to remain in effect for a period of up to three years, a requirement that registrants give notice of change of address is particularly appropriate.

SECTION 515

Currently, 21 U.S.C. 843(a)(2) prohibits the use of a registration number that is fictitious, revoked, suspended, or issued to another person. Section 515 of the bill adds to this list of prohibited acts the use of a registration number that has expired. Thus, this amendment cures the loophole in current law regarding use of an expired registration number and clarifies the legal status of a registrant who has failed to reapply for registration.

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[41] Clear authority to forfeit controlled substances possessed in violation of the Controlled Substances Act is added in section 517 of the bill.

SECTION 516

Addressing the serious problem of illicit diversion of legally produced drugs requires the concerted effort not only of Federal agencies, but of State and local law enforcement and regulatory agencies as well. However, for a number of reasons, many States and localities simply do not have the capacity to effectively address this problem.[42] Section 516 would provide a means of increasing the ability of States and localities to deal with the diversion problem by allowing the Attorney General to enter into grant-in-aid programs with State and local governments "to assist them to suppress the diversion of controlled substances from legitimate medical, scientific, and commercial channels." Funds appropriated for these grant-in-aid programs are to remain available until expended.

In its formal statement submitted to the Subcommittee on Criminal Law, the Department of Justice indicated that implementation of the grant-in-aid program would be preceded by an evaluation of the capabilities and needs of the States. Grants would be based on this evaluation and used for specific efforts aimed at diversion control. Moreover, the grants would be for specified terms with appropriate matching funds provided by the State.[43]

SECTION 517

Currently, controlled substances manufactured, distributed, dispensed, or acquired in violation of the Controlled Substances Act are subject to forfeiture under 21 U.S.C. 881(a)(1). Section 517 would amend this provision to include controlled substances that are possessed in violation of law. This amendment alleviates the problem now posed when a registrant has lawfully acquired controlled substances, but continues to possess them after his registration has expired or been terminated. In such situations, controlled substances are often left in unsecured or vacant buildings and so pose a serious risk of theft and danger to the public safety. Section 517 of the bill would give the Attorney General the authority to place such controlled substances under seal, retain them for safekeeping, and eventually dispose of them pursuant to forfeiture proceedings.[44]

SECTION 518

Under current 21 U.S.C. 952(a)(2), the importation of controlled substances in Schedules I and II and narcotic substances in Schedules III, IV, and V for medical, scientific, and other legitimate purposes is generally limited to those cases in which there is a finding that competition among domestic manufacturers is inadequate. This requirement has created difficulties in situations which routinely arise when researchers need specific substances for compara-

[42] Crime Control Act Hearings (statement of the Department of Justice, pp. 80–82).

[43] *Ibid.*

[44] The amendment to 21 U.S.C. 824 set out in section 511 of the bill requires that the Attorney General, when placing under seal controlled substances of a registrant whose registration has expired or ceased to do business, hold the substances for the benefit of the registrant for a period of 90 days. Only after the expiration of this 90-day period may the substances be forfeited and disposed of.

tive studies on foreign-developed compounds that are unique in their manufacture. Section 518 would accommodate the need to import such substances by adding a new provision to 21 U.S.C. 952(a)(2) that would allow importation of limited quantities of controlled substances for purposes exclusively of ultimate scientific, analytic, or research uses.

SECTION 519

Section 519 amends 21 U.S.C. 952(b)(2) by authorizing the Attorney General to require import permits for nonnarcotic Schedule III substances. Currently such permits are required for importation of narcotic Schedule III substances, but are not required for other Schedule III substances with high abuse potential unless such substances are listed in Schedule I or II of the Convention on Psychotropic Substances.[45] It is appropriate that import controls extend to all dangerous drugs classified in Schedule III of the Controlled Substances Act.

SECTION 520

Section 520 of the bill amends 21 U.S.C. 953(e) to tighten the criteria for export of controlled substances which are nonnarcotic Schedule III or IV substances or Schedule V substances. Under 21 U.S.C. 953(e)(1), export of these controlled substances is not permitted unless documentary proof is submitted showing that importation is not contrary to the laws or regulations of the "country of destination." Section 520 amends this provision to make it clear that the required documentation is to relate to the country where the controlled substance is destined for ultimate consumption for medical, scientific, or other legitimate purposes, and not to a country of transhipment. Section 520 of the bill also amends 21 U.S.C. 953(e) to require an export permit for nonnarcotic, as well as narcotic, Schedule III substances. This latter amendment parallels the requirement for import permits for all Schedule III substances provided in section 519 of the bill.

SECTION 521

Under current 21 U.S.C. 957(a)(2) registration is required of all persons exporting controlled substances in Schedules I, II, III, and IV, unless exemption from the registration requirement is specifically provided in 21 U.S.C. 952(b). Section 521 of the bill would extend this registration requirement to exporters of Schedule V substances. This amendment will eliminate confusion and bring the export requirements into conformity with all other registration requirements of the Controlled Substances Act.

SECTION 522

Section 522 modifies and clarifies the criteria for registration of an exporter or importer of Schedule I and II controlled substances under 21 U.S.C. 958(a). Under current section 958(a), the Attorney

[45] An example of a Schedule III substance not now subject to the controls of 21 U.S.C. 952(b)(2) is phendimetrazine, a highly abused anorectic (appetite suppressant) drug used as a substitute for amphetamines.

General is to register the applicant exporter or importer if the registration is consistent with the public interest and the obligations of the United States under international treaties, conventions, and protocols. In determining whether registration is in the public interest, the Attorney General is to consider the factors enumerated in 21 U.S.C. 823(a) which apply to registration of manufacturers of Schedule I and II substances.

Section 522 would amend 21 U.S.C. 958(a) so that the factors bearing on whether registration is in the public interest are listed in the section itself. These factors are largely based on those now appearing in 21 U.S.C. 823(a). However, the factor bearing on the adequacy of the measures to prevent diversion has been broadened. Currently, 21 U.S.C. 823(a)(1) refers to control against diversion by limiting the number of import and manufacturing establishments. While this should continue to be a consideration with respect to the factor of diversion control, it should not be the only element considered. Also, the factor set out in 21 U.S.C. 823(a)(3) relating to the applicant's promotion of technical advances in manufacturing is not carried forward since it bears no relevance to the application of an exporter or importer. Other differences between the factors specified in current 21 U.S.C. 823(a) and those added to 21 U.S.C. 958(a) by section 522 of the bill largely reflect the differences in the activities of manufacturers as opposed to importers and exporters.

SECTION 523

Under current 21 U.S.C. 958(b) a person registered to import or export Schedule I or II substances may import or export only those controlled substances specified in his registration. In contrast, the registrations of importers and exporters of substances in Schedules III, IV, and V are not drug specific. Thus, this latter category of registrants can trade in any and all substances in the Schedule for which they are registered, and the ability of the government to monitor import and export activity with respect to drugs of special interest in Schedules III, IV, and V is consequently inhibited. Section 523's amendment of 21 U.S.C. 958(b) would cure this problem by allowing the registrations of those exporting or importing any controlled substance to be limited to trading in specific controlled substances within particular schedules.

SECTION 524

Section 524 amends 21 U.S.C. 958(c) by listing the factors to be considered in determining whether registration of a person seeking to import or export controlled substances in Schedules III, IV, and V[46] is in the public interest. Currently, the factors to be considered for registration of exporters and importers are the same as those applicable to manufacturers and distributors of the same Schedule substances under 21 U.S.C. 823. As was done with respect to the registration criteria for importers and exporters of Schedule I and

[46] Under current 21 U.S.C. 957(a)(2), persons exporting Schedule V controlled substances are not required to register. This provision of current law is amended in section 521 of the bill to require registration of exporters of Schedule V controlled substances. Thus, section 524's amendment of the criteria for registration of exporters under 21 U.S.C. 958(c) encompasses Schedule V exporters as well.

II substances in section 522 of the bill, section 524 amends current law to specify the factors of consideration in 21 U.S.C. 958, rather than cross-referencing the factors specified in 21 U.S.C. 823. The factors added to 21 U.S.C. 958(c) are virtually identical to those added to 21 U.S.C. 958(a) in section 522 of the bill, as discussed *supra.*

SECTION 525

Section 525 of the bill amends 21 U.S.C. 958 by inserting a new subsection (d)[47] which specifies the procedures that are to apply for denial, revocation, or suspension of the registration of an exporter or importer of controlled substances. Currently, the procedures governing such determinations with respect to domestic manufacturers, distributors, and dispensers of controlled substances under 21 U.S.C. 824 are made applicable to importer and exporter registrations by virtue of a cross-reference to section 824 in 21 U.S.C. 958(d). The procedures added to 21 U.S.C. 958 with respect to the registration of importers and exporters are virtually identical to those now appearing in 21 U.S.C. 824. Like those in 21 U.S.C. 824, they require the Attorney General to serve on the applicant or registrant an order to show cause why his registration should not be denied, revoked, or suspended. The applicant must appear and respond within thirty days, and the proceedings are governed by the requirements of the Administrative Procedure Act.[48] If there is an "imminent danger to the public health and safety," the Attorney General may suspend the registration of an exporter or importer simultaneously with the institution of proceedings under new subsection (d). The provision in current 21 U.S.C. 958(d) incorporating by reference the denial, revocation, and suspension procedures of 21 U.S.C. 824 is deleted.

Section 525 also amends current 21 U.S.C. 958(h) (redesignated as subsection (i)) which gives registered domestic manufacturers of bulk controlled substances an opportunity for a hearing with respect to the registration application of an importer. The amendment in section 525 makes it clear that such manufacturers are to have an opportunity to present their views on the adequacy of competition among domestic manufacturers. It also removes the requirement of a hearing, which has considerably slowed the process of reviewing import and export applications. Thus, this section will retain the opportunity for domestic manufacturers to raise pertinent issues regarding an import registration application, but will speed the process of approving registration so that new applicants can enter the market, provided they can demonstrate to the Attorney General that they meet the stringent registration requirements.

SECTION 526

Section 526 amends 21 U.S.C. 952 (A)(1) to allow the import of poppy straw and its concentrate in amounts that the Attorney Gen-

[47] Current subsections (d) through (h) of 21 U.S.C. 958 are redesignated as subsections (e) through (i).

[48] 5 U.S.C. 500 et seq.

eral determines are necessary to medical, scientific, and other legitimate purposes, in the same manner as now provided for crude opium and coca leaves. Import of poppy straw and its concentrate has occurred for several years under emergency import authority.